Utilization Review Policy 228

POLICY: Oncology (Injectable) – Blenrep Utilization Management Medical Policy

- Blenrep™ (belantamab mafodotin-blmf intravenous infusion – GlaxoSmithKline)

EFFECTIVE DATE: 12/1/2020
LAST REVISION DATE: 10/29/2025

COVERAGE CRITERIA FOR: All UCare Plans

OVERVIEW

Blenrep, a B-cell maturation antigen (BCMA)-directed antibody and microtubule inhibitor conjugate, is indicated for treatment of relapsed or refractory **multiple myeloma**, in adults who have received at least two prior therapies including a proteasome inhibitor and an immunomodulatory drug in combination with bortezomib and dexamethasone.[1]

The FDA granted accelerated approval to Blenrep in August 2020 for the treatment of relapsed or refractory multiple myeloma in adults who have received at least four prior therapies, including an anti-CD38 monoclonal antibody, a proteasome inhibitor, and an immunomodulatory drug. This approval was based on overall response rate from an open-label, Phase II study. Because the primary endpoint (progression-free survival) was not met in the confirmatory Phase III study, Blenrep was withdrawn from the market in 2023. In October 2025, Blenrep received a new FDA approved indication in the third line setting for relapsed or refractory multiple myeloma.

Guidelines

National Comprehensive Cancer Network (NCCN) multiple myeloma guidelines (version 3.2026 – November 3, 2025) recommend Blenrep + bortezomib + dexamethasone for relapsed or refractory disease after two prior therapies including an immunomodulatory drug and proteasome inhibitor as "other recommended regimen" (category 1). Blenrep monotherapy is also recommended for relapsed or refractory disease after 3 prior lines of therapy as "useful in certain circumstances" (category 2A).[2]

POLICY STATEMENT

Prior Authorization is recommended for medical benefit coverage of Blenrep. Approval is recommended for those who meet the **Criteria** and **Dosing** for the listed indication. Extended approvals are allowed if the patient continues to meet the Criteria and Dosing. Requests for doses outside of the established dosing documented in this policy will be considered on a case-by-case basis by a clinician (i.e., Medical Director or Pharmacist). All approvals are provided for the duration noted below. Because of the specialized skills required for evaluation and diagnosis of patients treated with Blenrep as well as the monitoring required for adverse events and long-term efficacy, approval requires Blenrep to be prescribed by or in consultation with a physician who specializes in the condition being treated.

Automation: None.

RECOMMENDED AUTHORIZATION CRITERIA

Coverage of Blenrep is recommended in those who meet the following criteria:

FDA-Approved Indication

1. **Multiple Myeloma.** Approve for 1 year if the patient meets ALL of the following (A, B, C, D, and E):
   - **A)** Patient is ≥ 18 years of age; AND
   - **B)** Patient has tried at least two systemic regimens; AND
   - **C)** Among the previous regimens tried, the patient has received at least one drug from each of the following classes (i and ii):
     - **i.** Proteasome inhibitor; AND
       Note: Examples include bortezomib, Kyprolis (carfilzomib intravenous infusion), and Ninlaro (ixazomib capsules).
     - **ii.** Immunomodulatory drug; AND
       Note: Examples include lenalidomide, Pomalyst (pomalidomide capsules), and Thalomid (thalidomide capsules).
   - **D)** The medication will be used in combination with bortezomib and dexamethasone; AND
   - **E)** The medication will be prescribed by or in consultation with an oncologist.

   Dosing. Approve up to 2.5 mg/kg as an intravenous infusion with subsequent doses separated by at least 3 weeks.

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Coverage of Blenrep is not recommended in the following situations:

1. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

REFERENCES

1. Blenrep™ intravenous infusion [prescribing information]. Research Triangle Park, NC: GlaxoSmithKline; February 2022.
2. The NCCN Multiple Myeloma Clinical Practice Guidelines in Oncology (version 3.2026 – November 3, 2025). © 2025 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on November 4, 2025.

HISTORY

Type of Revision	Summary of Changes	Review Date
Annual Revision	No criteria changes.	09/28/2022
Selected Revision	**Multiple Myeloma:** Due to withdrawal from the market, a requirement was added to limit approval to a patient who is currently receiving Blenrep.	01/18/2023
Annual Revision	No criteria changes	09/27/2023
UCare P&T Review	Policy reviewed and approved by UCare P&T committee. Annual review process	09/16/2024
UCare P&T Review	Policy reviewed and approved by UCare P&T committee. Annual review process	09/15/2025
Annual Revision	**Multiple Myeloma**: The requirement that the patient is currently taking Blenrep was removed. The requirement that the patient has tried an anti-CD38 monoclonal antibody was removed along with the note of examples of an anti-CD38 monoclonal antibody. The requirement that the medication will be used in combination with bortezomib and dexamethasone was added. The dosing section was modified to reword "intravenously" to "intravenous infusion."	10/29/2025